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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Timothy BATEMAN et al.

erial No. 10/643,923

Art Unit: 3763

iled: August 20, 2003

Examiner:

For:

OOCYTE AND EMBRYO

HANDLING APPARATUS

Atty Docket: 0119/0025

SUBMISSION OF PRIORITY DOCUMENTS

Assistant Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Attached hereto please find certified copies of applicants' priority applications as follows:

United Kingdom Patent Application No. 0220146.5 filed August 30, 2002 United Kingdom Patent Application No. 0313392.3 filed June 11, 2003

Applicants request the benefit of said August 20, 2003 and June 11, 2003 filling dates for priority purposes pursuant to the provisions of 35 USC 119.

Respectfully submitted,

Louis Woo, Reg. No. 31,730 Law Offices of Louis Woo 717 North Fayette Street

Alexandria, Virginia 22314

Phone: (703) 299-4090

Date:

17 2004







The Patent Office Concept House Cardiff Road Newport South Wales NP10 8QQ

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Dated 29 July 20



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OÖCYTE RECOVERY SYSTEMS

This invention relates to oöcyte recovery systems.

In vitro fertilisation techniques require the removal of oöcytes from the uterus of a woman and subsequent fertilisation outside the body. It is important that the handling of the oöcytes minimises damage. One possible source of damage to the oöcytes and consequent reduced fertility rates is due to thermal shock. During removal, the environment of the oöcytes changes from being at body temperature to a lower temperature, closer to room temperature.

It is an object of the present invention to provide an alternative occyte recovery system and method.

According to one aspect of the present invention there is provided an oöcyte recovery system including a tube for passage of the oöcyte and a heated jacket extending along a part at least of the length of the tube.

According to another aspect of the present invention there is provided an oöcyte recovery system including a tube for passage of the oöcyte and a heated jacket in which the tube is insertable so that the jacket extends along a part at least of the length of the tube.

The system preferably includes a source of heated fluid and a conduit extending between the source and the jacket so that heated fluid flows within the jacket and warms the tube. The jacket preferably includes a central bore and two outer channels, the central bore being adapted to receive the tube as a sliding fit and the outer channels being adapted to receive heated fluid such that the fluid extends along one channel in one direction and along the other channel in the opposite direction. The two outer channels are preferably of C shape in section and extend along opposite sides of the tube. The jacket is preferably extruded of a flexible plastics material.

According to a third aspect of the present invention there is provided an oöcyte recovery system including a tube for passage of the oöcyte, a source providing a flow of warmed fluid, a first channel connected with the source and extending along a major part of the length of the tube so that warmed fluid from the source flows forwardly from the rear end of the tube, and a second channel opening into the first channel towards the forward end of the tube so that fluid flows rearwardly along the second channel.

According to a fourth aspect of the present invention an oöcyte recovery method includes the steps of connecting a tube to an oöcyte recovery needle, warming the tube along a part at least of its length with a warming fluid, applying suction to the tube to draw an oöcyte into the tube and collecting the oöcyte after passage through the warmed length of tube.

An oöcyte recovery system according to the present invention, will now be described, by way of example, with reference to the accompanying drawing, which is a perspective view of the system.

The system includes a conventional oöcyte recovery tube or catheter 1 connected at its forward end 2 to a conventional oöcyte recovery needle 3. At its rear end 4, the tube 1 is connected to a collection test tube 5 to which suction is applied so that the recovered oöcytes are collected in the tube, in the usual way.

The system also includes a warming arrangement indicated generally by the numeral 10. The warming arrangement 10 comprises an electrically-heated fluid warmer 11, such as of the kind sold under the trade mark HOTLINE (a Registered Trade Mark of Level 1, Inc) by Level 1, Inc of Rockland, Massachusetts, USA. The fluid warmer 11 provides a recirculating flow of water warmed to about 39°C. The warmer 11 is connected by a dual-bore tubing 12 to a heat exchanger 13. The tubing 12 has two bores 14 and 15, one for the warmed water flowing away from the warmer 11 and the other for the returned water flowing back to the warmer for reheating.

The heat exchanger 13 is preferably a modified version of that used with the HOTLINE warmer for warming infusion fluid supplied to a patient. The heat exchanger 13 is described in detail in US 5063994 and in US 5097898. The heat exchanger 13 is extruded from a plastics material to form a flexible, elongate, tubular jacket of circular external section. The exchanger 13 has three bores extending in parallel along the length of the exchanger. A central bore 16 is provided by a tubular portion 6 of circular section supported by two radially-extending webs 17 and 18. The webs 17 and 18 bisect an outer concentric passage around the central bore 16 into two outer channels 19 and 20 each having a C shape section. The central bore 16 opens axially at the rear end 21 of the exchanger 13 through as an end cap 22. The outer channels 19 and 20 communicate via the cap 22 with respective

ones of the bores 14 and 15 of the tubing 12 and hence communicate with the fluid warmer 11. The forward end 23 of the exchanger 13 similarly has an end cap 24 within which the two outer channels 19 and 20 communicate with one another so that water supplied forwardly along one channel can flow back rearwardly along the other channel. The central bore 16 opens axially through the forward end cap 24.

The oöcyte recovery tube 1 extends through the central bore 16 of the heat exchanger 13 as a close sliding fit to ensure that there is a good thermal contact between the tube and the tubular portion 6, thereby promoting efficient heat transfer to the tube. The bore 16 or tube 1 may be coated with a lubricant such as a gel to ease insertion of the tube in the bore and to improve thermal contact. The heat exchanger 13 extends along most of the length of the recovery tube 1 apart from a short section 25 at its forward end, which is exposed to facilitate manipulation, although the flexible nature of the heat exchanger does allow the remainder of the tube to be easily manoeuvred.

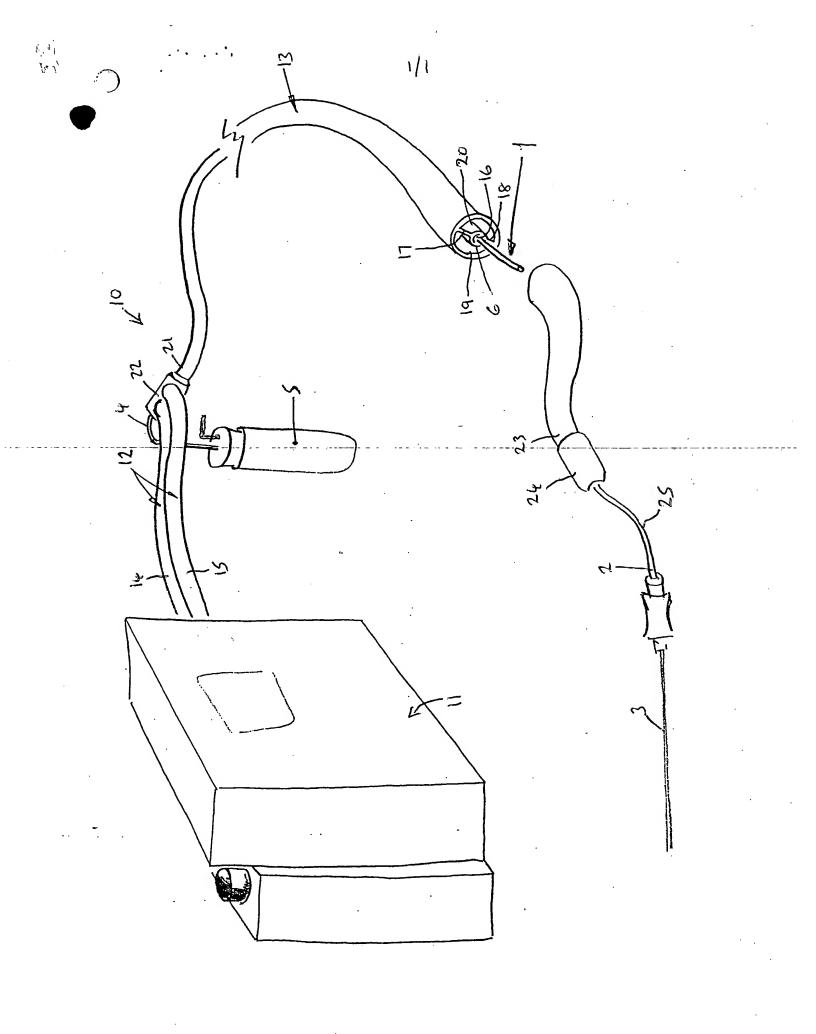
In an alternative arrangement, the recovery tube would not project from the heat exchanger and, instead, the hub of the needle would be combined with the end cap of the heat exchanger. Such an arrangement has the advantage of enabling the entire length of the oöcyte recovery tubing to be warmed. In order to ensure that the needle could still be manipulated freely it would be preferable for the material of the heat exchanger to be selected for maximum flexibility.

In use, the fluid warmer 11 supplies warmed water at about body temperature to the rear end 21 of the exchanger 13, which flows forwardly along one channel 19 and then

rearwardly along the other channel 20. This ensures that the occyte recovery tube 1 is maintained very close to body temperature so as to maintain the recovered occytes close to their ideal temperature during recovery.

Although alternative forms of heat exchanger could be used, the arrangement described, where fluid is supplied to and returned from the exchanger at its rear end, has several advantages. First, it keeps the forward end of the exchanger free of any additional tubing so that the surgical site is kept uncluttered and so that there is less impediment to manipulation of the forward end of the tube and exchanger. Second, the drop in temperature of the heated water flowing forwardly along the length of the exchanger is in the opposite sense to that of the water flowing rearwardly. This has the effect of reducing the overall temperature gradient along the length of the exchanger, which minimizes the thermal shock to which the oöcytes are exposed.

The oöcyte recovery tube could be inserted in the heat exchanger by the user and removed after use so that the heat exchanger can be reused. There is no risk of contamination because there is no direct contact with the heat exchanger itself. Alternatively, the recovery tube could be fixed irremovably within the heat exchanger so that the tube and exchanger are provided together as a single unit and are disposed of together after use. The tubular portion providing the central bore of the heat exchanger could itself provide the oöcyte recovery tube.



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